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| 10/693,698 | 10/27/2003 | Farid Bruce Khalili | VER2226-003 | 2291 |

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| EXAMINER | |
|---|---|
| HOFFMAN, MARY C | |
| ART UNIT | PAPER NUMBER |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/693,698 | KHALILI, FARID BRUCE | |
| | Examiner | Art Unit | |
| | MARY HOFFMAN | 3733 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12/18/2007, 04/03/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *2,3,5-10,24,36-42 and 68-72* is/are pending in the application.

4a) Of the above claim(s) *2,3,5-10 and 70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24, 36-42, 68-69, 71-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 June 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Newly submitted claim 70 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 70 is directed to a non-elected embodiment, Species A.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 70 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

In addition, Applicant has pointed out that the embodiment shown in FIGS. 12A-B lacks a seat ring; accordingly, this embodiment is now grouped with Species A.

### *Specification*

On page 3 of the specification, in Applicant's brief description on FIGS. 12A-B, the specification states that that FIGS. 12A-B are cross-sectional views of a pedicle screw and rod system according to Fig. 11. As Applicant pointed out in his remarks section, FIGS. 12A-B lack the seat ring of FIG. 11. Therefore, FIGS. 12A-B are not "cross-sectional views of a pedicle screw and rod system according to Fig. 11" as stated in the specification.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 69 and 37-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 69 recites the limitation "the seat sleeve" in line 6. There is insufficient antecedent basis for this limitation in the claim.

Dependent claims 69 and 37 recite the limitation "an enlarged head". It is unclear whether this refers to the same "enlarged head" as is recited in independent claim 68, or if it is a different feature. Applicant is reminded that the "enlarged head" of claim 68 refers to both the head of the bone screw as well as the seat ring.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 68, 71 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman et al. (U.S. Patent No. 5,879,350) in view of Bono et al. (U.S. Patent No. 6,755,829).

Sherman et al. disclose a spinal rod system for bridging one or more adjacent vertebrae, the system comprising a first and a second fastener assembly, each having a first end (tip of bone screw, see FIG. 2) adapted to be driven into vertebral bone, an intermediate portion (ref. #21) threaded for bone purchase and a second end with an enlarged head (ref. #22 and 13); a first and a second rod retention assembly (FIG. 5), each rod retention assembly comprising a cup with an open top end and an open bottom end, the bottom end of each rod retention assembly providing a generally circular opening that is larger than the intermediate portion of the fastener assembly and is smaller than the enlarged head of the fastener assembly, the open top end of each cup comprising a top opening defined by a generally cylindrical wall which comprises two diametrically opposed slots (ref. #33) that extend downwardly from the uppermost portion of the generally cylindrical wall. Each fastener assembly is arranged in the associated cup to be locked with respect to the cup by progressive tightening of the respective screw

Sherman et al. disclose a method of bridging a pair of adjacent vertebrae in a stabilizing manner, comprising the steps of Inserting the first and second fastener assemblies into the respective first and second rod retention cups; installing the intermediate portions of the respective fastener assemblies into the adjacent vertebrae, one fastener assembly in each vertebra; positioning the rod into the diametrically opposed slots of each of the rod retention assemblies so that the rod extends at least between the respective cups; and installing a cap into each rod retention assembly atop the rod and tightening the cap such that a portion of the rod inside the cup is retained

therein and the tightening locks angular orientation of the fastener assembly relative to the rod retention assembly.

Sherman et al. disclose the claimed invention except for the claimed closure mechanism, i.e. at least two inverted shoulders, each inverted shoulder having a contact surface inclined in a direction radially outwardly from a center axis of the cup; a cap being generally cylindrically shaped and having at least two shoulders extending radially outward and each having a shoulder with a contact surface inclined in a direction radially outwardly from a center of the cap, the system further comprising a screw inserted through a screw hole in the cap to apply pressure to the rod in order to progressive tighten and lock the rod relative to the cup.

Bono et al. disclose a closure mechanism comprising at least two inverted shoulders, each inverted shoulder having a contact surface inclined in a direction radially outwardly from a center axis of the cup; a cap being generally cylindrically shaped and having at least two shoulders extending radially outward and each having a shoulder with a contact surface inclined in a direction radially outwardly from a center of the cap (FIG. 6A-6C), the system further comprising a screw inserted through a screw hole in the cap to apply pressure to the rod in order to progressive tighten and lock the rod relative to the cup (col. 6, lines 23-27), in order to provide a quick twist-lock closure cap adaptable to diverse reduction screws (col. 2, lines 1-9 and lines 51-54).

It would have been obvious to one of ordinary skill in the art to combine to bone screw assembly of Sherman et al. with the closure mechanism comprising at least two inverted shoulders, each inverted shoulder having a contact surface inclined in a

direction radially outwardly from a center axis of the cup; a cap being generally cylindrically shaped and having at least two shoulders extending radially outward and each having a shoulder with a contact surface inclined in a direction radially outwardly from a center of the cap, the system further comprising a screw inserted through a screw hole in the cap to apply pressure to the rod in order to progressive tighten and lock the rod relative to the cup in view of Bono et al. to provide a quick twist-lock closure cap adaptable to diverse reduction screws

Claims 36-42, 68-69 and 71-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlapfer (U.S. Patent No. 6,063,090) in view of Bono et al. (U.S. Patent No. 6,755,829).

Schlapfer discloses a spinal rod system for bridging one or more adjacent vertebrae, the system comprising a first and a second fastener assembly, each having a first end adapted to be driven into vertebral bone, an intermediate portion (ref. #2) threaded for bone purchase and a second end with an enlarged head (ref. #9,7); a first and a second rod retention assembly, each rod retention assembly comprising a cup (ref. #20) with an open top end and an open bottom end, the bottom end of each rod retention assembly providing a generally circular opening that is larger than the intermediate portion of the fastener assembly and is smaller than the enlarged head of the fastener assembly, the open top end of each cup comprising a top opening defined by a generally cylindrical wall which comprises two diametrically opposed slots (ref. #11) that extend downwardly from the uppermost portion of the generally cylindrical wall. Each fastener assembly is arranged in the associated cup to be

locked with respect to the cup by progressive tightening of the respective screw. The bone fastener assembly comprises a hemispherical enlarged head (ref. #9) and a seat ring (ref. #34). An inwardly tapered conical surface is formed on the interior of the cup and surrounding the bottom opening. A seat spacer (ref. #12) is adapted to rest on top of each the bone screw fastener head and to be positioned beneath the rod, thereby supporting the rod relative to the bone screw the fastener. The top surface of each bone screw the fastener head is generally dome-shaped and each the seat spacer has a complementary contact surface that contacts the top surface of the respective bone screw fastener head in a manner permitting angular adjustment of the respective bone screw relative to the seat spacer. A method of bridging a pair of adjacent vertebrae in a stabilizing manner is disclosed, comprising the steps of Inserting the first and second fastener assemblies into the respective first and second rod retention cups; installing the intermediate portions of the respective fastener assemblies into the adjacent vertebrae, one fastener assembly in each vertebra; positioning the rod into the diametrically opposed slots of each of the rod retention assemblies so that the rod extends at least between the respective cups; and installing a cap into each rod retention assembly atop the rod and tightening the cap such that a portion of the rod inside the cup is retained therein and the tightening locks angular orientation of the fastener assembly relative to the rod retention assembly. The step of inserting the fastener assemblies into the respective rod retention assemblies comprises the substeps of inserting a seat ring into each of the rod retention cups, and inserting a bone screw into each of the rod retention cups and through a central opening in the seat

ring, such that intermediate portion of each bone screw extends outwardly from the rod retention cup and the seat ring, interposed between the head of the bone screw and the bottom opening of the rod retention cup, retains the bone screw in the rod retention cup in a angularly adjustable manner.

Schlapfer discloses the claimed invention except for the claimed closure mechanism, *i.e.* at least two inverted shoulders, each inverted shoulder having a contact surface inclined in a direction radially outwardly from a center axis of the cup; a cap being generally cylindrically shaped and having at least two shoulders extending radially outward and each having a shoulder with a contact surface inclined in a direction radially outwardly from a center of the cap, the system further comprising a screw inserted through a screw hole in the cap to apply pressure to the rod in order to progressive tighten and lock the rod relative to the cup.

Bono et al. disclose a closure mechanism comprising at least two inverted shoulders, each inverted shoulder having a contact surface inclined in a direction radially outwardly from a center axis of the cup; a cap being generally cylindrically shaped and having at least two shoulders extending radially outward and each having a shoulder with a contact surface inclined in a direction radially outwardly from a center of the cap (FIG. 6A-6C), the system further comprising a screw inserted through a screw hole in the cap to apply pressure to the rod in order to progressive tighten and lock the rod relative to the cup (col. 6, lines 23-27), in order to provide a quick twist-lock closure cap adaptable to diverse reduction screws (col. 2, lines 1-9 and lines 51-54).

It would have been obvious to one of ordinary skill in the art to combine to bone screw assembly of Schlapfer with the closure mechanism comprising at least two inverted shoulders, each inverted shoulder having a contact surface inclined in a direction radially outwardly from a center axis of the cup; a cap being generally cylindrically shaped and having at least two shoulders extending radially outward and each having a shoulder with a contact surface inclined in a direction radially outwardly from a center of the cap, the system further comprising a screw inserted through a screw hole in the cap to apply pressure to the rod in order to progressive tighten and lock the rod relative to the cup in view of Bono et al. to provide a quick twist-lock closure cap adaptable to diverse reduction screws

***Response to Arguments***

Applicant's arguments filed 12/18/2007 have been fully considered but they are not persuasive.

The collet of Sherman can be considered part of the "enlarged head", therefore, the device of Sherman meets the claims as currently written. Regarding Applicant's argument that the Sherman device is used by popping the bone screw head upwardly, this argument is irrelevant, since the current claims do not exclude a bone fixation system of this type.

The rejections are deemed proper.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARY HOFFMAN whose telephone number is (571)272-5566. The examiner can normally be reached on Monday-Thursday 10:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary C. Hoffman/
Examiner, Art Unit 3733

/Anu Ramana/
Primary Examiner, Art Unit 3733